



User Manual



Contacts

USA: 1-877-988-9388 (Toll Free)

E-mail: support@resperate.com

United Kingdom: 0800-177-7778 (Toll Free)

E-mail: support@resperate.co.uk

Israel: +972-73-220-7000

E-mail: support@resperate.co.il

Other Countries: +1-646-652-5800 (USA)

When the RESPeRATE device has reached the end of its useful life, dispose of it according to local regulations.

Manufactured by InterCure Ltd.

www.intercure.com

Copyright © 2002–2013 InterCure, Ltd. All rights reserved. RESPeRATE®, RESPeRATE Ultra™, and InterCure® are trademarks of InterCure.

Table of Contents

Introduction	3
Using Your RESPeRATE Device	7
I. RESPeRATE Device and Display	7
II. Set Up	13
III. Using Your RESPeRATE for the 1st Time	15
IV. Using RESPeRATE Daily	19
V. Tips	22
Functions.....	24
I. Melody Selection	24
II. Guiding Arrows	25
III. Mute	26
IV. Default Session Duration	26
Performance Statistics.....	27

Troubleshooting..... 36

- I. Troubleshooting.....36
- II. Manual Sensor Positioning.....39

Additional Product Information..... 40

- I. RESPeRATE Limited Warranty 40
- II. Cleaning and Maintenance.....41
- III. Technical Information 42
- IV. Country Specific Market Clearance 47
- V. Indication for Use 48
- VI. Customer Support.....50

RESPeRATE To Lower Blood Pressure

Introduction

Congratulations on the purchase of your RESPeRATE, the first medical device clinically proven to lower blood pressure in an effective and pleasant way.



Please note: RESPeRATE should only be used as part of your overall health program for achieving goal blood pressure, as recommended by your doctor. RESPeRATE can be safely used in conjunction with medication and lifestyle modifications such as diet and exercise.

The therapeutic power of breathing

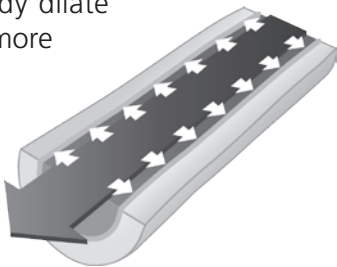
The therapeutic power of breathing has been known for centuries and is used predominantly in relaxation techniques such as meditation and yoga. Modern science has, only recently, confirmed that certain therapeutic breathing exercises, performed without conscious effort, can significantly lower blood pressure. The problem is that these exercises can be difficult to perform effectively on your own without years of training and individualized coaching. RESPeRATE makes therapeutic breathing easy to do on your own.

Breathing with RESPeRATE makes the difference

RESPeRATE's patented "Device Guided Breathing" technology ingeniously takes advantage of the body's natural tendency to follow musical rhythms.

RESPeRATE automatically analyzes your individual breathing pattern. It then creates a personalized melody composed of two distinct tones – a high inhale tone and a low exhale tone. By prolonging the tones, RESPeRATE guides you into the Therapeutic Breathing Zone without any conscious effort on your part.

The physiological result? The muscles surrounding the small blood vessels in your body dilate and relax. Blood is allowed to flow more freely, and pressure is significantly lowered. After each exercise with RESPeRATE, your breathing returns to its normal rate and pattern. Nevertheless, the beneficial effect on blood pressure will accumulate.

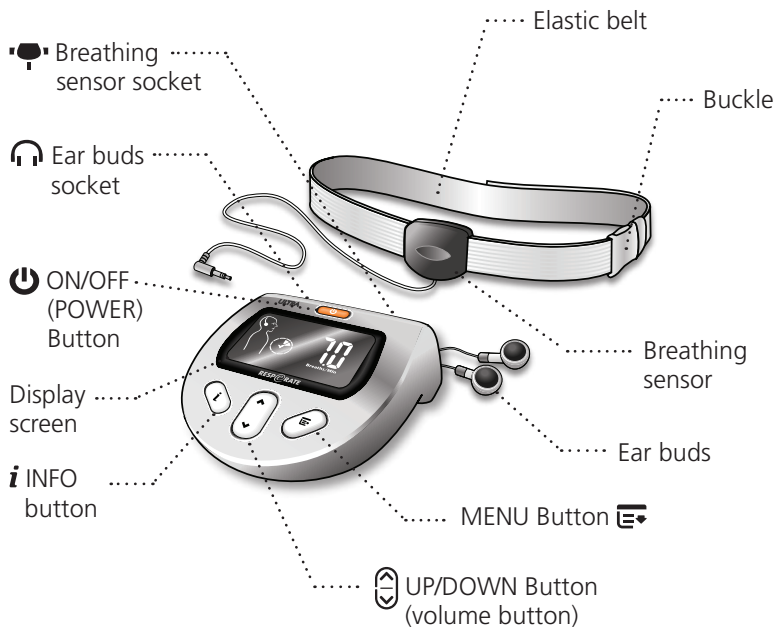


To Achieve Best Results

- Create a relaxing environment for your RESPeRATE sessions. Sit in a comfortable chair in a quiet room with minimal distractions.
- Therapeutic breathing occurs when you are breathing slower than 10 breaths per minute, with prolonged exhalation and without a conscious effort.
- Your goal is to log at least 10 minutes of slow therapeutic breathing per session. Significant reductions and all day blood pressure lowering can be achieved by accumulating at least 40 minutes of therapeutic breathing per week.
- Additional use may provide even better results. RESPeRATE has a normalizing effect and will not lower your blood pressure below a healthy level. Daily sessions, if possible, are recommended.
- Be patient. As with any physical exercise program, you can expect to see notable progress within 3-4 weeks.

Using Your RESPeRATE Device

I. RESPeRATE Device and Display



Main Display

The following values appear here:

- Breaths per minute
- Volume level
- Melody selection number
- Session duration (minutes)
- Therapeutic minutes
- Statistics

User # 1
(Duo model)

User # 2
(Duo model)

Low Battery

Guiding Figure

(with guiding arrows and notes)

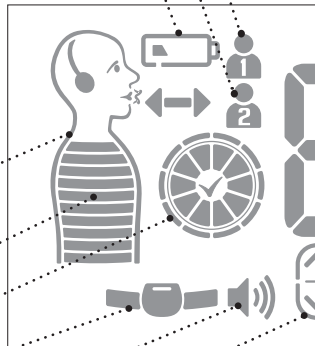
Breathing Gauge

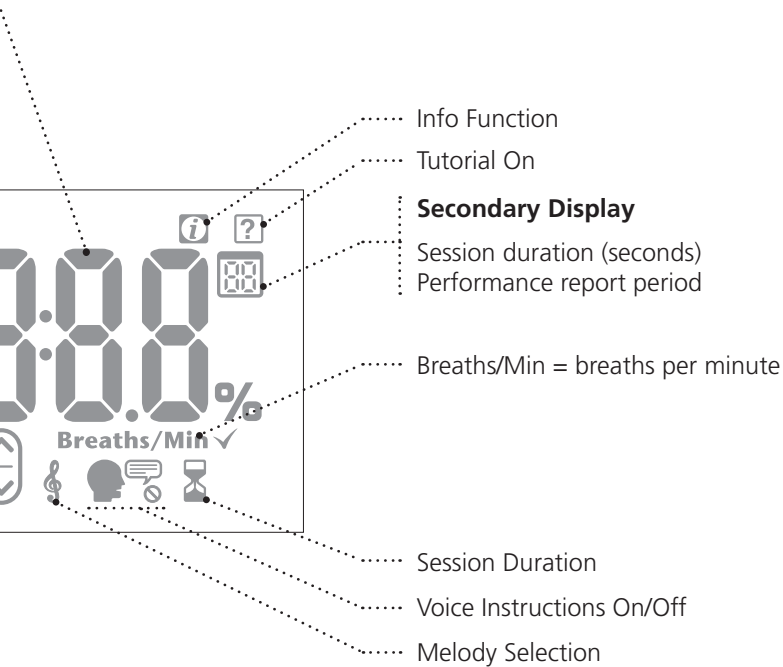
Therapeutic Minutes Clock

Sensor Belt Errors (tight/loose/improper)

Volume

Scroll Up/Down & Volume

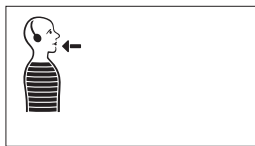




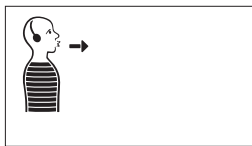
Recognition Phase

Each session begins with a Recognition phase. During this phase background music will play and a figure showing your breathing movements will appear on the screen.

The figure fills up as you breathe in and empties as you breathe out.

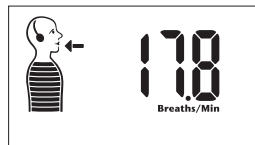


Breathe In



Breathe Out

You should relax and breathe while RESPeRATE learns your breathing rate and pattern. Once RESPeRATE has successfully learned your breathing pattern it will display your current breaths per minute (Breaths/min) on the screen.



Breaths per minute

Breathing Exercise Phase

RESPeRATE composes a melody based on your individual breathing pattern. It contains two distinct guiding tones. The high tone signals to “breathe in” and the low tone signals to “breathe out”. Synchronize your breathing, inhaling and exhaling gradually, with the tones.

To help you get started, voice instructions  will be provided for the first few breaths. Continue to breathe according to the inhale and exhale tones and they will guide you into the therapeutic breathing zone.

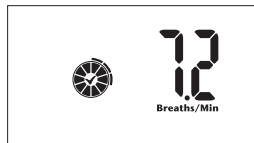
Therapeutic Minutes

When your breathing rate is below 10 breaths per minute you enter the therapeutic breathing zone. RESPeRATE will tell you when this occurs and the “Therapeutic Minutes Clock” icon will appear on the screen.



Therapeutic
Minutes Clock

Each minute spent in the Therapeutic Breathing Zone appears as a filled segment in the clock. When the clock fills in completely, you have successfully spent 10 minutes in the therapeutic breathing zone. Each additional minute will now be displayed as a ring outside of the clock.



Clock with Ring

To achieve best results, accumulate **at least 40 minutes** of therapeutic breathing per week. For your convenience, RESPeRATE momentarily displays the therapeutic minutes accumulated in the past 7 days each time you turn on the device. *When starting to use RESPeRATE, this number will show "0" minutes. Once you start using the device and accumulating therapeutic minutes, this number will show a "running tab" of your last 7 days.* It will never show "0" minutes again unless you have accumulated zero therapeutic breathing time for 7 consecutive days.

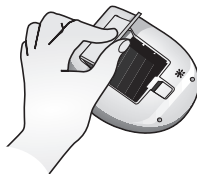
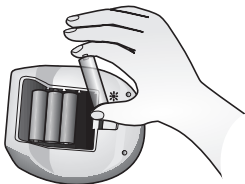


42.5-Therapeutic
Minutes for the past
7 days

II. Set Up

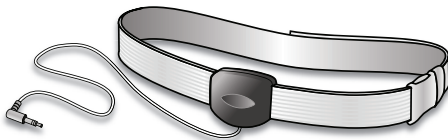
1. Install the batteries

Place the 4 AA batteries into the battery compartment located on the bottom of the device. Position the batteries as shown inside the compartment.



2. Plug in the sensor

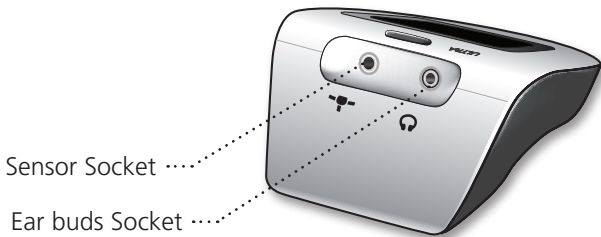
Insert the sensor plug into the smaller socket in the back of the device marked with "⚡".



3. Plug in the ear buds

Insert the ear buds plug into the socket at the back of the device marked with .

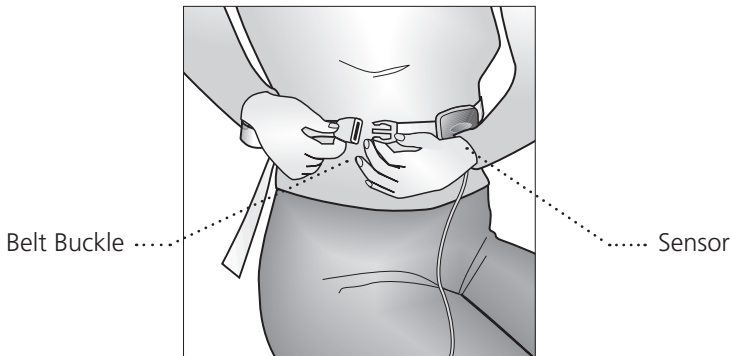
Sponges for the ear buds are provided should you need them. Please note that any standard headphones can be used with RESPeRATE.



III. Using Your RESPeRATE for the 1st Time

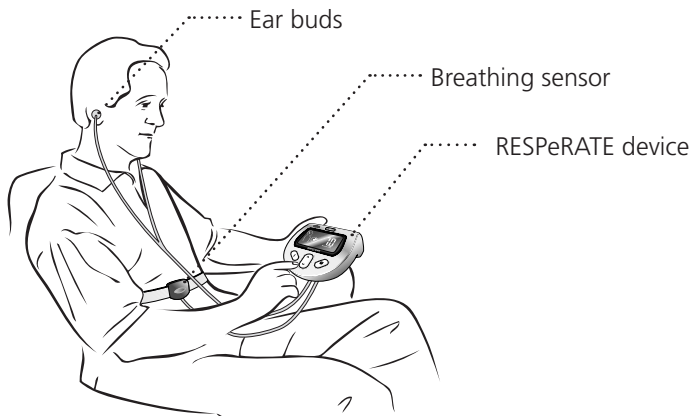
1. Putting on the sensor belt

The belt should be wrapped around your upper abdomen, halfway between your navel and chest, and buckled. Buckling the belt in front, as illustrated, will be more convenient. The label of the sensor is to be placed against your body and the sensor cable should hang down. The sensor belt should not be on too tightly. Slide the sensor slightly to the left and right to ensure that it can move freely.



2. Putting in the ear buds and leaning back

It is important to make sure that your breathing is not being limited in any way. Loosen restrictive clothing (tight pants, belt, etc) and place the device in a comfortable position such as on your lap or a nearby table. It's important to avoid leaning forward which may limit the breathing movement of the abdomen or chest.

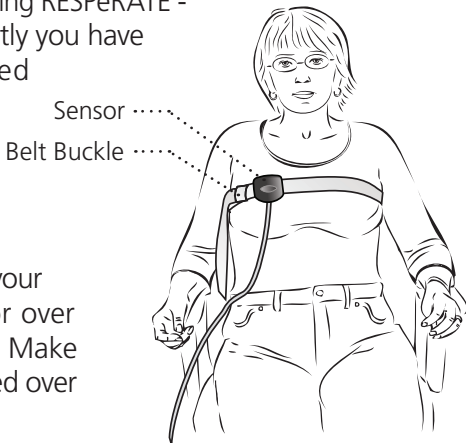


Breathing exercise with RESPeRATE

The Tutorial

When using RESPeRATE for the first time, start by using the Tutorial. It will check your sensor position, guide you through an abbreviated session, and provide additional information. It takes about 10 minutes to complete and will familiarize you with RESPeRATE.

The Tutorial will determine where you should position the sensor while using RESPeRATE - abdomen or chest. Currently you have the sensor belt wrapped around your upper abdomen. During the Tutorial you may be instructed to move the sensor belt to your chest. If so, move the belt above your chest and slide the sensor over to the right as illustrated. Make sure the sensor is not placed over a bra strap.



Chest sensor position

3. Activating the Tutorial

To activate, press and hold the POWER button  until you see  icon appear on the screen. While in the Tutorial, put aside all distractions and listen to the voice instructions.



IV. Using RESPeRATE Daily

Turning on RESPeRATE

To begin a session, turn on the device by pressing the POWER button . The recognition phase will begin and your initial breaths per minute will be displayed.

Next a session will begin in which your breathing will be guided by musical tones into the therapeutic breathing zone.

Each session and every breath will bring you closer to achieving and maintaining your goal blood pressure.

For RESPeRATE Duo Model

The duo model is capable of storing performance data for two different users on one device. However, only one person can use the device at a time.

After the device has been turned on, select User 1  or User 2  by pressing the UP/DOWN button  respectively.

If a user is not selected within the first 5 seconds, the device will default to function and store information for the last user.

Adjusting the Volume

To adjust the volume press the UP/DOWN button  until you reach your preferred level (1-15). When you press the button, the current level will be displayed on the screen. After you adjust, the new level will be displayed for a few seconds and then return to the previous screen.

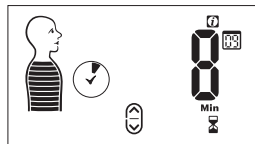


Volume Display

You can adjust the volume at any time while using RESPeRATE. It will be stored as the last set volume for the next session.

Viewing/Changing Session Duration

To view how much time you have left in a session, press the INFO button  and it will be displayed on the right of the screen.



Session Duration -
Remaining Time

RESPeRATE sessions are set for a default time of 15 minutes. If you would like to extend or shorten the time, press the INFO button **i** and then the UP/DOWN button  until you reach your preferred time. The change will only apply to the particular session. Changing default session duration is explained in the functions section.

Status Feedback

At any point during a session you can press the INFO button **i** to receive feedback. RESPeRATE will tell you if you are or are not following the tones. If you are having some difficulty, the device will suggest a solution. If you continue to have difficulties, the “Troubleshooting” section of the user manual can provide answers.

Refresh Function

If at any time during the session you feel that following the guiding tones is uncomfortable, press and hold the INFO button **i**.

The guiding tones stop temporarily, allowing you to breathe comfortably with quiet background music. RESPeRATE adjusts itself to your comfortable breathing pattern and then continues the guiding tones. The therapeutic minutes accumulated will not be affected.

V. Tips

Breathe effortlessly. In order to effectively lower blood pressure, it is essential to breathe effortlessly during the entire RESPeRATE session. Normal breathing is usually 12–18 breaths per minute. In the first few sessions, your slowest comfortable breathing rate achieved might be higher than 10 breaths per minute. Don't push yourself. Within a few RESPeRATE sessions, your breathing rate will likely drop to below 10 breaths per minute.

Breathe gradually. While following the guiding tones avoid holding your breath after inhaling or exhaling. Breathing excessively deep is counterproductive. Effortless breathing is best achieved by a gradual inhalation through the nose, then a gradual exhalation through the mouth. One easy way to prolong exhalation is to purse your lips as if you were blowing out a candle. If at any time during the session you feel that following the guiding tones is uncomfortable, use the Refresh function by pressing and holding the INFO button **i**.

It's not a competition. The slowest breathing rate and pattern that is comfortable for each individual varies from person to person and from day to day. Only you can decide when breathing becomes uncomfortable. The goal is to reach the Therapeutic Zone of slower

than 10 breaths per minute, not to reach as slow a breathing rate as possible. Making an effort to achieve an excessively slow breathing rate may not be as beneficial in lowering blood pressure levels.

The more therapeutic breathing minutes, the better!

Be sure to accumulate no less than 40 therapeutic breathing minutes per week. Remember that the more time spent in the Therapeutic Breathing Zone, the better your chances of achieving greater blood pressure reduction.

Avoid other breathing techniques. During the RESPeRATE session, don't try other breathing techniques such as breath-holding or Buteyko. These types of breathing require effort which is counter-productive to lowering blood pressure.

Stay awake to lower blood pressure. RESPeRATE is very relaxing. Some users have been known to fall asleep. When sleeping, your breathing rate may become faster and you will not accumulate therapeutic minutes. You may use RESPeRATE to fall asleep as a secondary purpose.

Be patient. As with any physical exercise program, long term results are not immediate. Each session can provide an immediate sense of calm and relaxation. However, an all-day blood pressure reduction starts to be seen within - 3-4 weeks.

Functions

Your RESPeRATE can be adjusted based on your preferences. The following section will explain how to set the functions to your likings. The functions are listed according to the order they appear when the MENU button  is pressed.

To select a function, press the MENU button  and then press the UP/DOWN button  to reach your preferred setting. RESPeRATE will return to the previous screen after the change is made and it will save the change for the next session.

I. Melody Selection

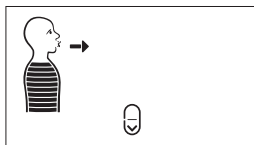
To select a different melody, press the MENU button  **one (1) time**. Then press the UP/DOWN button  to reach your preferred melody. The melody icon  and the selected melody number will appear on the screen.



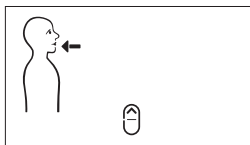
Melody Display

II. Guiding Arrows

The guiding arrows depict when to breathe in and when to breathe out. By default they will turn off one minute into a session as some people tend to constantly focus on them. However, if you are having problems following the tones or prefer to have the visual aid, you can activate them.



Guiding Arrows On



Guiding Arrows Off

To turn the guiding arrows on/off, press the MENU button  **two (2) times**. Then press the UP button to turn it on and the DOWN button to turn it off. Your display will change accordingly.

III. Mute

During the session voice instructions and warnings will be spoken. However, if they become a distraction they can be muted.



Voice Instructions On



Voice Instructions Off

To turn the voice instructions on/off, press the MENU button  **three (3) times**. Then press the UP button to turn it on or the DOWN button to mute. Your display will change accordingly.

IV. Default Session Duration

To change the default session duration press the MENU button  **four (4) times**. Then press the UP/DOWN button to increase/decrease the time. The time changes in increments of 5 minutes. Sessions can range between 10 and 60 minutes.



Session Duration

Performance Statistics

Performance statistics track and provide feedback on your performance using RESPeRATE. This feature is optional and is not necessary to lower blood pressure.

The two simplest ways to assess your performance are the therapeutic minutes clock icon (during session) and the weekly therapeutic breathing time (displayed momentarily on the device display when it is turned on).

For a more advanced assessment, RESPeRATE's built-in memory stores the following six statistics related to your performance: number of sessions, therapeutic minutes, initial breathing rate, final breathing rate, synchronization, and breath detection.

Furthermore, each of these performance statistics is provided for three different time periods: last session, last 7 days, and last 30 days.

To View Performance Statistics

1. When RESPeRATE is off, press and hold the INFO button **i** until the screen displays the statistic. The data that appears is for your last session.

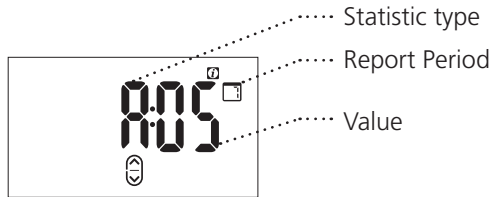
For the Duo Model, first select User 1  or User 2  to view the results for the appropriate user.

2. Press the UP/DOWN button  to browse between the performance statistics.
3. To choose a time period other than your last session press the INFO button **i**. **Press it once to view data for the last 7 days and twice to view data for the past 30 days.**

To Understand Performance Statistics Display

Performance statistics are expressed as shown in the example: a letter and a value together with the Report Period.

The letter corresponds to the statistic type and range from A to F. The value shows the performance for that particular statistic. The report period varies depending on the time frame selected.



Performance Display

Performance Statistics

Statistic A: Number of Sessions

The number of sessions that reached the breathing exercise phase.

Description	Example
<u>Last session</u> report reads A:01 After your first RESPeRATE session, this value will always be "1."	
<u>Last 7 days</u> report reads A:05 Means that in the past 7 days, 5 sessions reached the guided breathing exercise period.	
<u>Last 30 days</u> report reads A:54 Means that in the past 30 days, 54 sessions reached the guided breathing exercise period.	

Statistic B: Therapeutic Minutes

Amount of Time (in minutes) spent in the therapeutic breathing zone. The goal is to accumulate at least 10 therapeutic minutes per session and 40 minutes per week.

Description	Example and Goal
<u>Last session</u> report reads b:9.5 Means that 9.5 minutes were spent in the therapeutic zone during the last Session.	 Goal > 10 Min
<u>Last 7 days</u> report reads b:46 Means that a total of 46 minutes were spent in the therapeutic zone over the last 7 days.	 Goal > 40 Min
<u>Last 30 days</u> report reads b:46 Means that on average, 46 minutes per week of use were spent in the therapeutic zone. Note: If value is 100 or greater (therapeutic minutes), a blinking "99" appears.	 Goal > 40 Min

Statistic C: Initial Breathing Rate

Number of breaths per minute at the beginning of the breathing exercise phase. The acceptable range is between 6-30 breaths per minute.

Description	Example and Acceptable Range
<u>Last session</u> report reads C:17 Means that the initial breathing rate was 17 breaths per minute. Initial breathing rates are “normal” levels and typically vary from 12 to 18 breaths per minute.	
<u>Last 7 days</u> report reads C:17 Means that the average initial breathing rate was 17 breaths per minute.	
<u>Last 30 days</u> report reads C:17 Means that the average initial breathing rate was 17 breaths per minute.	

Statistic D: Final Breathing Rate

Number of breaths per minute at the end of the RESPeRATE session. The recommended range is 5-10 breaths per minute.

Description	Example and Recommended Range
<u>Last session</u> report reads d:6.2 Means that the final breathing rate was 6.2 breaths per minute. Final breathing rates vary and can typically reach 6–8 breaths per minute within a few weeks of use.	
<u>Last 7 days</u> report reads d:6.2 Means that the average final breathing rate was 6.2 breaths per minute.	
<u>Last 30 days</u> report reads d:6.2 Means that the average final breathing rate was 6.2 breaths per minute.	

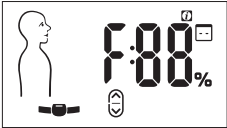
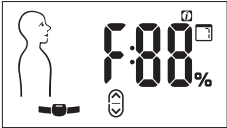
Statistic E: Synchronization

Indicates how well you are following the guiding tones. Specifically, it is the percentage of time in which breathing was synchronized with the guiding tones. The acceptable range is from 60-99%.

Description	Example and Acceptable Range
<u>Last session</u> report reads E:94 means that 94% of the time, breathing was synchronized with the guiding tones.	 
<u>Last 7 days</u> report reads E:94 Means that on average , 94% of the time, breathing was synchronized with the guiding tones.	 
<u>Last 30 days</u> report reads E:94 Means that on average , 94% of the time, breathing was synchronized with the guiding tones.	 

Statistic F: Breath Detection

Indicates how well the sensor is able to recognize inhalation and exhalation as a result of the placement of the sensor. Specifically, it is the percentage of session time that the breathing sensor could identify the respiration data. This should range from 80-99%.

Description	Example and Recommended Range
<u>Last session</u> report reads F:88 Means that 88% of the time, sensor was able to identify respiration data.	 The image shows a digital display with a silhouette of a person wearing a sensor. The display shows 'F:88%' with a small '7' icon in the top right corner. Below the silhouette is a small icon of the sensor device.
<u>Last 7 days</u> report reads F:88 Means that on average 88% of the time the sensor was able to identify the respiration data.	 The image shows a digital display with a silhouette of a person wearing a sensor. The display shows 'F:88%' with a small '7' icon in the top right corner. Below the silhouette is a small icon of the sensor device.
<u>Last 30 days</u> report reads F:88 Means that on average 88% of the time the sensor was able to identify the respiration data.	 The image shows a digital display with a silhouette of a person wearing a sensor. The display shows 'F:88%' with a small '7' icon in the top right corner. Below the silhouette is a small icon of the sensor device.

Troubleshooting

I. Troubleshooting

The table below describes some situations which may occur and how to best solve them. If your particular problem is not addressed, contact customer service.

Problem	Explanation	Solution
The Recognition Phase takes longer than two minutes.	The sensor is improperly positioned.	Refer to Tutorial and Manual Sensor Positioning section (page 39)
	Breathing is too unstable	Relax and breathe normally.
I repeatedly hear a voice message, "Breathe with the guiding tones."	Breathing is not synchronized with the guiding tones.	Begin to gently inhale then, gradually exhale soon after the start of the guiding tones.
		Activate the guiding arrows for assistance.
		Try following Melody #4.

Problem	Explanation	Solution
I am unable to complete sensor positioning in the tutorial	Breathing is not synchronized with the voice instructions.	Begin to gently inhale then, gradually exhale soon after the voice instructions.
One or both of the guiding tones are too fast or too slow for my current breathing to the point I'm uncomfortable or lightheaded.	Your breathing rate has changed abruptly.	RESPeRATE will adapt within a few breaths to guide you according to your natural breathing pattern.
	You are following the tones but feel uncomfortable or lightheaded.	Use the Refresh function by pressing and holding the INFO button i . RESPeRATE will re-calibrate to your comfortable breathing pattern.
Breath per Minutes display is flashing.	You are breathing more than 30 or less than 3 breaths per minute.	Breathe according to the guiding tones.
The display does not turn on when the device is turned on.	Batteries need to be replaced. This icon  indicates battery power.	Install new batteries.
	The +/- poles of the batteries are positioned incorrectly.	Reinstall the batteries with the +/- poles positioned correctly.

Problem	Explanation	Solution
Music is not heard through the ear buds.	The volume is not high enough.	Press the Up button to increase the volume level.
	The Ear buds are not connected properly to the device.	Reconnect the ear buds to the device. A click will sound when they are properly inserted.
	RESPeRATE automatically switched off because the session is over.	Restart to begin a new session.
Static noise is heard through the ear buds.	Ear buds are not fully plugged into the ear buds socket.	Reconnect the ear buds to the device. A click will sound when they are properly inserted.
	Electronic communication device (cell phone, beeper, etc) is operating within 5 feet of RESPeRATE	Remove electronic communication device while conducting the session.

II. Manual Sensor Positioning

The Tutorial should determine where you are to position the sensor – abdomen or chest. If you are experiencing difficulty, there is an alternative way to assess the appropriate position. First, any restrictive clothing (tight pants belt or bra) should be loosened. Second, too many layers (heavy sweaters/sweatshirts) may disrupt the signal and should be removed.

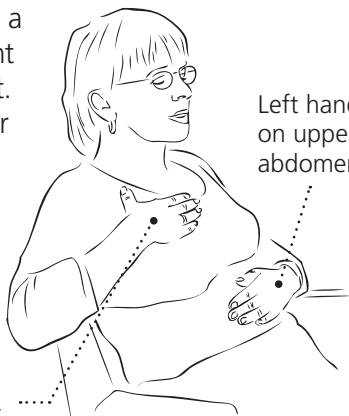
If the issue persists, try manual sensor positioning. Sit comfortably on a chair. Lean back and place your right hand on the right side of your chest. Place your left hand on the upper abdomen, above the navel.

Take a few breaths. Feel which hand moves first when you start to inhale and exhale. The sensor position is determined by which hand moves first.

Place the sensor accordingly.

Right hand on
right chest

Left hand
on upper
abdomen



Manual sensor positioning

Additional Product Information

I. RESPeRATE Limited Warranty

RESPeRATE is warranted to be free from manufacturing defects for a period of one year from date of purchase under normal use. This warranty extends only to the original purchaser. Should repair be needed within the warranty period, please call RESPeRATE Customer Support. We will either repair or replace (at our discretion) free of charge any parts necessary to correct defects in the materials or workmanship.

If it is necessary to replace the entire product, it may be replaced with a remanufactured product. The above warranty is complete and exclusive. The warrantor expressly disclaims liability for incidental, special, or consequential damages of any nature.

To ensure activation of your warranty, please complete the registration form online at: www.resperate.com/register.

Some counties and/or states do not allow the exclusion or limitation of incidental or consequential damages, so the above warranty may not apply to you. Any implied warranties arising by the operation of law shall be limited in duration to the term

of this warranty. This warranty gives you specific legal rights, and you may have other rights which vary from state to state.

II. Cleaning and Maintenance

To clean RESPeRATE, use a soft, slightly damp cloth. Do not wash the sensor or the RESPeRATE device. Do not use petroleum products, thinners, or cleaning solvents!

Protect your RESPeRATE against excessive vibrations.

Do not leave your RESPeRATE in a place where temperatures are below -14°F (-10°C) or above 158°F (70°C), or in conditions of very high humidity (>85%).

Do not attempt to make repairs of any kind on RESPeRATE. Contact Customer Care if repairs are necessary.

Please use only Alkaline batteries.

If you do not plan to use RESPeRATE for a period of more than two months, remove batteries from the battery compartment to avoid damaging the device.

III. Technical Information

Model Name: RESPeRATE™, RESPeRATE Duo™ and RESPeRATE Deluxe™ (RESPeRATE Ultra™ is a marketing name of RESPeRATE™);

Model #: RR152, RR152D, RR152-1M, RR152-1DM, RR152-1, RR152-1D

Display type: LCD; The Deluxe™ edition includes a back light that makes it easier to read the screen in the dark or in poor light;

Power source: four alkaline batteries, 1.5V (type AA);

Battery life: two months, with regular use of 15 minutes per day;

Maximum audio output: 10mW with 16 Ohm Ear buds;

Device display respiration rate: range of 2-42 BPM but guides between 5-20 BPM;

Operating temperature: 10°C - 40°C (50°F - 104°F);

Operation humidity: 30 - 75%;

Storage temperature: -10°C - 70°C (14°F - 158°F);

Storage humidity: 30 - 85%;

Weight: 360 grams;

Outer product dimensions: 12.4 L x 11.7 W x 6.6 H cm,
4.9" L x 4.6" W x 2".6 H

Expected Service Life: 5 years

Guidance and manufacturer's declaration – electromagnetic immunity

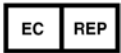
The RESPeRATE is intended for use in the electromagnetic environment specified below. The customer or the user of the RESPeRATE should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	Not applicable	Not applicable.
Surge IEC 61000-4-5	± 1 kV line(s) and neutral	Not applicable	Not applicable.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5s	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the RESPeRATE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation Distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RESPeRATE is used exceeds the applicable RF compliance level above, the RESPeRATE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RESPeRATE. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

The symbols that appear on the labelling have the following meanings:

Symbol	Description
	Disposal according to Local Regulation for Electronic Devices
	Manufacturer
	Consult Instructions For Use
	CE mark
	Type BF Applied Part
	Authorized representative in the European community
	Keep dry

IV. Country Specific Market Clearance

United States: 510(k) number K020399 (OTC) and K000405 (Rx)

European Union: CE 0473

Israel: Ministry of Health number 237-0000

South Korea: Korean KFDA 04-259

Canada: Health Canada 63948

Thailand: ISR 4700595

China: SFDA 2260351

V. Indication for Use

RESPeRATE is intended for use as a relaxation treatment for the reduction of stress by leading the user through interactively guided and monitored breathing exercises. The device is indicated for use only as an adjunctive treatment for high blood pressure together with other pharmacological and/or non-pharmacological interventions. Over-the-counter.

Contraindication: None known.

Precautions: Do not use this device without consulting your physician if you suffer or have suffered in the past from: active ischemic heart disease/unstable angina, severe congestive heart failure, chronic arterial fibrillation, stroke resulting in permanent impairment, chronic renal failure, severe asthma, chronic obstructive pulmonary disease (COPD), like chronic bronchitis and emphysema, major organ failure or sleep paralysis, have a pacemaker or if you are pregnant.

InterCure strongly recommends that you do not modify your hypertension treatments without the advice and consent of your physician.

Do not use your RESPeRATE when you need to be alert or to

concentrate, or when using heavy equipment. Do not use RESPeRATE while driving. If you experience any side effects or if you feel any change in your general health or mood, immediately discontinue use of your RESPeRATE, and contact your physician.

Breathe effortlessly throughout the exercise. Excessive deep breathing may cause dizziness and palpitations.

If you experience a rash or irritation from using the ear buds, discontinue use and consult a physician.

Warning: No modification of this equipment is allowed

Warning: Do not connect the RESPeRATE to any other devices or equipment

Transport the RESPeRATE in its carrying case

Contact InterCure to report any unexpected operation or event associated with the use of the device or if you require any assistance in operating the device.

Please note: RESPeRATE should only be used as part of your overall health program for achieving goal blood pressure, as recommended by your doctor. RESPeRATE can be safely used in conjunction with medication and lifestyle modifications such as diet and exercise.

VI. Customer Support

RESPeRATE **Customer Care Representatives** are available for guidance and support. If you have any questions or feedback, call Customer **Care Department** to speak or schedule a call.

You can also post your questions or feedback on the RESPeRATE User Forum at www.resperate.com/forum

USA: 1-877-988-9388 (Toll Free)

E-mail: support@resperate.com

United Kingdom: 0800-177-7778 (Toll Free)

E-mail: support@resperate.co.uk

Israel: +972-73-220-7000

E-mail: support@resperate.co.il

Other Countries: +1-646-652-5800 (USA)

Manufactured by:

InterCure®
Interactive Therapeutic Devices

For more information or customer service:
www.resperate.com

USA: 1-877-988-9388 (Toll Free)
United Kingdom: 0800-177-7778 (Toll Free)
Israel: +972-73-220-7000
Other Countries: +1-646-652-5800 (USA)

Manufacturer Authorized Representative in Europe:

 MEDES Ltd.

9, Beaumont Gate, P.O.Box 231
Shenley Hill, Radlett, Herts
London WD78BX, UK
tel/fax: +44 (0) 192 385 9810

InterCure, Inc
356 Bloomfield Ave, Office 5
Montclair, NJ 07042, USA

InterCure, Ltd
The Forum Business Centre
Lansdown Road, Cheltenham
Gloucestershire, GL50 2JA, England

 InterCure, Ltd
16 Hatidhar st. P.O Box 4131
Raanana 43652, Israel

www.intercure.com



0473

721 E 0100 D



User Manual